## Food and Drug Administration, HHS

- (2) Indications for use. For the treatment and control of large strongyles: Strongylus vulgaris (adults and L4/L5 arterial stages), S. edentatus (adult and tissue stages), Triodontophorus brevicauda (adults), and T. serratus (adults); small strongyles (adults): (Cyathostomum spp., including C. catinatum and C. pateratum; Cylicocyclus insigne, C. nas including *C.* and leptostomum, Cylicostephanus spp., including C. calicatus, C. goldi, C. longibursatus, and C. minutus; Coronocyclus spp., including C. coronatus, C. labiatus, and C. labratus; and Gyalocephalus capitatus; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: Parascaris equorum (adults and L4 larval stages); pinworms: *Oxyuris* equi (adults and L4 larval stages); Trichostrongylus hairworms: (adults); large-mouth stomach worms: Habronema muscae (adults); horse stomach bots: Gasterophilus intestinalis (2nd and 3rd instars) and G. nasalis (3rd instars); and tapeworms: Anoplocephala perfoliata (adults). One dose also suppresses strongyle egg production for 84 days.
- (3) *Limitations.* For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

 $[68\ FR\ 51446,\ Aug.\ 27,\ 2003,\ as\ amended\ at\ 69\ FR\ 21956,\ Apr.\ 23,\ 2004]$ 

### §520.1468 Naproxen granules.

- (a) *Specifications*. Naproxen granules contain 50 percent naproxen.
- (b) *Sponsor*. No. 000856 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Horses. The drug is used for the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.
- (2)(i) For oral maintenance therapy following initial intravenous dosage, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as top dressing in the animal's feed for up to 14 consecutive days. The initial intravenous dosage is 5 milligrams per kilogram of body weight.

- (ii) For oral dosage only, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as a top dressing in the animal's feed for up to 14 consecutive days.
- (3) Not for use in horses intended for food.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 14188, Apr. 2, 1976, as amended at 51 FR 24525, July 7, 1986; 61 FR 5506, Feb. 13, 1996]

# § 520.1484 Neomycin sulfate soluble powder.

- (a) *Specifications*. Each ounce of powder contains 20.3 grams of neomycin sulfate (equivalent to 14.2 grams of neomycin base).
- (b) Sponsors. See sponsors in \$510.600(c) of this chapter for use as in paragraph (d) of this section.
- (1) Nos. 000069 and 051259 for use as in paragraph (d)(1) of this section.
- (2) Nos. 000009, 046573, and 061623 for use as in paragraphs (d)(1) and (d)(2) of this section.
- (c) Related tolerances. See §556.430 of this chapter.
- (d) Conditions of use—(1) Cattle (excluding veal calves), swine, sheep, and goats.
- (i) Amount. 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) in divided doses for a maximum of 14 days.
- (ii) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.
- (iii) Limitations. Add to drinking water or milk; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.
- (2) Turkeys—(i) Amount. 10 milligrams of neomycin sulfate per pound of body

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weight per day (22 milligrams per kilogram) for 5 days.

- (ii) *Indications for use.* For the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys.
- (iii) *Limitations.* Add to drinking water; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 5 consecutive days.

[64 FR 31497, June 11, 1999, as amended at 66 FR 14073, Mar. 9, 2001; 67 FR 72366, Dec. 5, 2002; 67 FR 78971, Dec. 27, 2002; 68 FR 4914, Jan. 31, 2003]

# § 520.1485 Neomycin sulfate oral solution.

- (a) *Specifications*. Each milliliter contains 200 milligrams of neomycin sulfate (equivalent to 140 milligrams of neomycin base).
- (b) *Sponsors.* See Nos. 000009, 051259, and 059130 in §510.600(c) of this chapter.
- (c) *Related tolerances*. See §556.430 of this chapter.
- (d) Conditions of use—(1) Amount. 10 milligrams of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.
- (2) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats.
- (3) Limitations. Administer undiluted or in drinking water. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

[58 FR 38972, July 21, 1993, as amended at 60 FR 3079, Jan. 13, 1995; 61 FR 31398, June 20, 1996; 62 FR 60657, Nov. 12, 1997; 63 FR 45944, Aug. 28, 1998; 65 FR 45877, July 26, 2000; 65 FR 53581, Sept. 5, 2000]

#### § 520.1498 Nitazoxanide paste.

- (a) *Specifications*. Each milligram (mg) of paste contains 0.32 mg nitazoxanide.
- (b) Sponsor. See No. 065274 in \$510.600(c) of this chapter.
- (c) Conditions of use in horses—(1) Amount. On days 1 through 5, administer 11.36 mg per pound (/lb) body weight; on days 6 through 28, administer 22.72 mg/lb body weight.
- (2) Indications for use—For the treatment of equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 500, Jan. 6, 2004]

#### §520.1510 Nitenpyram tablets.

- (a) *Specifications*. Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.
- (b) Sponsor. See No. 058198 in \$510.600(c) of this chapter.
- (c) Special considerations. The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.
- (d) Conditions of use—(1) Dogs—(i) Amount—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.
- (B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.
- (ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.
- (B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in §520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in §520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.